

REMARKS

The Office Action dated July 2, 2008 has been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, claim 1 has been amended to recite that the ring opening polymerization is conducted in the presence of a ring-opening polymerization catalyst, as set forth in the present specification at page 15, lines 6-8, paragraph [0034]. Claims 10-12 are amended to correspond with claim 1. Claims 23-25 are added. Support for claims 23 and 25 may be found in the present specification at page 15, lines 6-8, paragraph [0034], while support for claim 24 may be found in claim 1 and the specification, for example at page 1, lines 6-14, paragraph [0001]. It is believed that these changes do not involve any introduction of new matter, whereby entry of the present amendment is in order and is respectfully requested.

Claims 1, 4, 6 and 10-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and the *Handbook of Thermoplastic Polymers*, Chapter 2, pages 80-94 (HTP). Claims 7-9 were rejected under 35 U.S.C. §103(a) as being obvious and unpatentable over this combination of references and further in view of Early (US 6,437,565). Applicants respectfully traverse these rejections and request reconsideration of the patentability of claims 1, 4 and 6-22.

As defined by claim 1, the invention is directed to a process for producing an aliphatic polyester by subjecting a cyclic ester to bulk ring-opening polymerization. The process comprises providing a cyclic ester purified to the extent that a water content is at most 50 ppm, an α -hydroxycarboxylic acid content is at most 100 ppm, and linear α -hydroxycarboxylic acid oligomers content is at most 1000 ppm, and controlling an over all proton concentration in a

ring-opening polymerization system by adding water to the cyclic ester. The overall protein concentration in the cyclic ester is calculated out on the basis of the total amount of hydroxycarboxylic compounds consisting of α -hydroxycarboxylic acid and the linear α -hydroxycarboxylic acid oligomer as impurities in the cyclic acid, water contained as impurities in the cyclic ester, and water added to the cyclic ester. The process further comprises subjecting the cyclic ester to ring opening polymerization in a closed state and in the presence of a ring-opening polymerization catalyst, thereby controlling melt viscosity of the resulting aliphatic polyester.

It has been found that when an aliphatic polyester such as polyglycolic acid is produced by ring-opening polymerization of a cyclic ester such as glycolide using a high-purity cyclic ester and water is added to the cyclic ester to control the overall proton concentration in the cyclic ester, the melt viscosity and the molecular weight of the formed polymer can be precisely controlled. The overall proton concentration in the cyclic ester is determined by the amount of water and hydroxycarboxylic compounds contained as impurities and the added water. It has not previously been known that the melt viscosity and molecular weight of an aliphatic polyester can be controlled by controlling the overall proton concentration in the cyclic ester with the addition of water. As demonstrated in the Examples and Comparative Examples in the present specification, the presently claimed process allows the production of aliphatic polyesters having good, precisely controlled melt viscosity, desired molecular weight, and low yellowing.

In the Official Action, the Examiner asserted that Shinoda discloses a preparation process of polyester with desirable MW (molecular weight) or melt viscosity, the Examiner noting that melt viscosity of a resulting aliphatic polyester polymer is a proportional function of the MW of the polyester, from cyclic esters or their mixtures, wherein impurities such as water

and hydroxycarboxylic acids (including oligomers) are accurately controlled (thus proton concentration also controlled) with total amount less than 100 ppm. The Examiner asserted that Shinoda is “silent about addition of water” to the polymerization system but asserted Howelton teaches addition of water as a polymerization initiator, referring to column 1, line 20 of Howelton.

Applicants submit however that, contrary to the Examiner’s assertion that Shinoda is silent about addition of water, Shinoda specifically teaches away from any addition of water to the cyclic ester. That is, Shinoda indicates that when the moisture content of the cyclic ester is high, molecular weight control of the polyester is liable to be difficult. Shinoda therefore discloses that the water content in the cyclic ester is preferably controlled to at most 100 ppm or less and that the moisture can be removed from the cyclic ester compound by known processes such as deairing or heat drying (see Shinoda, column 6, lines 37-52). Thus, while Shinoda does not disclose addition of water to the cyclic ester, Shinoda is not silent about water. Rather, Shinoda teaches that water is undesirable and should be removed, not added. Importantly, since Shinoda et al consider water as an impurity, it is apparent that a person of ordinary skill in the art would not have found the addition of water obvious in view of Shinoda.

On the other hand, Howelton is directed to carboxyl-terminated polyetheramines, not polyesters. While the Examiner has relied on Howelton et al as teaching addition of water as polymerization initiator in a ring-opening polymerization, the disclosure relied upon by the Examiner is in reference to nylon production in Howelton’s discussion of the prior art, namely:

“It is well known that polyamides such as nylon-5, nylon-6, nylon-8, and nylon-12 have been produced by ring-opening polymerization of appropriate lactams. Nylon-6, also called polycaprolactam, was originated by I. G. Farbenindustrie in 1940. In one preparation technique, the polymerization of ϵ -caprolactam (also known as ϵ -aminocaprolactam or simply caprolactam), is carried out by adding water to open the ring

and then removing water again at elevated temperature, where linear polymer forms. Caprolactam may also be polymerized by ionic chain mechanisms.” (see column 1, lines 13-23).

However, Howelton et al do not discuss a production process for producing an aliphatic polyester by subjecting a cyclic ester to bulk ring-opening polymerization and do not disclose any step of controlling an overall proton concentration. Although Howelton disclose that water can be used as an initiator in a process for producing carboxyl-terminated polyamides, the process of Shinoda, and that of claim 1, employs a ring-opening polymerization catalyst, and thus has no need for water to be added to initiate ring opening. Finally, and most importantly, Howelton provided no motivation or apparent reasoning for one of ordinary skill in the art to proceed contrary to the teaching of Shinoda that moisture should be removed, and to add water to Shinoda’s cyclic ester. Howelton’s reference to nylon production provides no such motivation or apparent reasoning.

The deficiencies of Shinoda and Howelton are not resolved by HTP. The ring-opening polymerization of the cyclic ester as recited in claim 1 is performed in a closed state so that the overall proton concentration in the cyclic ester is prevented from changing by mixing of water (moisture) in an external atmosphere. In order to precisely control the melt viscosity of the aliphatic polyester according to the process of the present invention, it is necessary to strictly control the polymerization reaction system in such a manner that the overall proton concentration, including the added water, is retained to a predetermined value. In contrast, HTP only states a general theory as to ring-opening polymerization and does not suggest the fact that the overall proton concentration, including the amount of added water, in the cyclic ester should be precisely controlled by conducting the polymerization reaction system in a closed state.

Additionally, at pages 90-94 referred to by the Examiner, HTP describes ring-opening polymerizations for polycaprolactone and polylactide production. Importantly, on page 94, HTP discloses that the cyclic dimer will contain neither water nor linear oligomers for production of polylactide. Thus, HTP, like Shinoda, teaches away from water addition. Further, while HTP indicates that the lack of volatile byproducts eliminates the requirement for a vacuum, Applicants find no teaching that the reaction should be conducted in a closed system as presently claimed, and Applicants particularly find no teaching or suggestion of the specific process steps and apparatus as recited in the present claims.

Early similarly fails to resolve the deficiencies of Shinoda and specifically fails to teach or suggest addition of water or any relation between the overall proton concentration in the cyclic ester and the melt viscosity of the aliphatic polyester. In view of this deficiency in the teachings of Early, Shinoda, Howelton, and HTP, the combinations of these references as asserted by the Examiner provide no motivation or apparent reasoning for one of ordinary skill in the art to add water to the cyclic ester of Shinoda on the basis of a relational expression between a predetermined overall protein concentration in the cyclic ester and a melt viscosity of the aliphatic polyester.

The Examiner's attention is again directed to the Examples and Comparative Examples set forth in the present specification beginning at page 38. These Examples and Comparative Examples include a comparison which demonstrates the improvements in the process and product provided by the claimed invention as compared with the exemplary teachings of Shinoda. More particularly, when 1-dodecyl alcohol (lauryl alcohol) as exemplified by Shinoda is added as the molecular weight control agent to conduct ring-opening polymerization of glycolide as shown in Comparative Example 3 in Table 1 of the present specification (page 43),

the weight average molecular weight of polyglycolic acid formed can be controlled with a measure of accuracy. However, the amount of volatile matter (residual monomer) contained in the polyglycolic acid is high, namely 0.55% by weight, and, as a result, the melt viscosity thereof is markedly low (1,560 Pa·s), even though it is a high-molecular weight polymer ($M_w = 181,000$). In contrast, when water is added as the molecular weight control agent to glycolide so as to control the overall proton concentration to a predetermined value in the ring-opening polymerization as shown in Examples 1-4 in Table 1, according to claim 1, polyglycolic acid having a desired corresponding high melt viscosity (3470-3630 Pa·s) and high weight average molecular weight (205,000-218,00) can be obtained. In addition, extremely little volatile matter is contained in the polyglycolic acid (0.01-0.11% by weight).

The Examiner previously stated that arguments directed to the amount of volatile matter are irrelevant to the claimed subject matter of claims 1 and 3-20. However, a comparison of the results of Comparative Example 3 with the results of Examples 1-4 shows that when a higher alcohol such as lauryl alcohol as exemplified by Shinoda is used as the molecular weight control agent (Comparative Examples), the weight average molecular weight of the resulting polymer can be controlled with a measure of accuracy, but a low melt viscosity undesirably results, and as shown in Table 1 of the present specification, the amount of volatile matter (residual monomer) is high. Accordingly, the amount of volatile matter is a measure of the improvement provided by the process of the present invention, with the desirable low volatile matter allowing better control of the melt viscosity of a resulting aliphatic polyester, in particular, allowing production of a high molecular weight aliphatic polyester having a correspondingly high melt viscosity as compared with the use of lauryl alcohol as exemplified by Shinoda.

Further, the results in Table 2 of the present specification (page 50) show that the amount of volatile matter in a ring-opening aliphatic polymer is high even when no water is added (Comparative Example 4). Therefore, the ring-opening polymer of Comparative Example 4 has an extremely low melt viscosity, 1,500 Pa·s, though it has the same weight average molecular weight (198,000) as the ring-opening polymer of Example 6 produced by adding water. However, the melt viscosity of the ring-opening polymer of Example 6 is 2,550 Pa·s, and it is apparent in view of the results of Examples 5, 7 and 8 that a good melt viscosity value corresponding to the weight average molecular weight value is attained according to the presently claimed process.

Although Applicants submit that the Examiner has not established a prima facie case of obviousness based on Shinoda, even in view of Howelton, HTP and Early, the showings set forth in the Examples and Comparative Examples of the present application rebut any prima facie case of obviousness established by the Examiner. That is, the results of Examples 1 to 4 in Table 1 and 5 to 8 in Table 2 of the present specification, according to the process of the present invention, show ring-opening polyglycolic acids having a relatively high melt viscosity can be obtained by adding water as claimed. In addition, Examples 7 and 8 particularly show a tendency to remarkably improve the yellowness index (YI), even in a region wherein the melt viscosity and weight average molecular weight are relatively low, when water is used as the molecular weight control agent. A ring-opening polymer low in both melt viscosity and yellowness index (YI) is desirable for use as a polymer for injection molding. Finally, Comparative Example 3 in Table 1 of the present specification shows that the yellowness index (YI) of the ring-opening polymer formed when lauryl alcohol is added as the molecular weight

control agent is high compared with that of the ring-opening polymers (Examples 6 and 7 in Table 2) each having a similar weight average molecular weight.

When an applicant demonstrates substantially improved results and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary, *In re Soni*, 34 U.S.P.Q. 2d 1684, 1688 (Fed. Cir. 1995). The Examples and Comparative Examples set forth in the present specification demonstrate substantially improved results provided by the process according to the present invention, Applicants have stated that the results were unexpected, and the Examiner has not provided any evidence to the contrary. In fact, the Examiner has repeatedly failed to acknowledge or comment on the substantially improved results set forth in the present specification. Thus, Applicants have rebutted any prima facie case of obviousness based on Shinoda.

The Examiner's effort to establish obviousness by showing that the addition of water may be found somewhere in the prior art, namely in the polyamide production of Howelton, is unavailing; in determining obviousness, the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention as a whole for which patentability is claimed. *Grain Processing v. American Maize*, 5 U.S.P.Q. 2d 1788, 1793 (Fed. Cir. 1988). More recently, the Supreme Court has stated that in determining patentability under 35 U.S.C. §103, it is necessary to determine whether there was an apparent reason to combine the known elements in the fashion of the claims at issue, *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740-41 (2007). Not only does Howelton fail to teach the addition of water to a cyclic ester, Howelton fails to teach or suggest improvements provided by the present process in controlling the melt viscosity of aliphatic polyesters, or any other reason to proceed contrary to the teachings of Shinoda that moisture should be removed. While Howelton teaches addition of

water to initiate nylon production, Shinoda's process, and that of claim 1, employ a ring-opening catalyst so that the water addition of Howelton is unnecessary. Accordingly, the cited prior art does not make the present invention as a whole obvious.

It is therefore submitted that the processes defined by present claims 1, 4 and 6-22 are nonobvious over and patentably distinguishable from the cited combination of Shinoda, Howelton, and HTP, or these references in further combination with Early, whereby the rejections under 35 U.S.C. §103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Official Action and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 503915.

Respectfully submitted,

/Holly D. Kozlowski/

Holly D. Kozlowski, Reg. No. 30,468
Porter, Wright, Morris & Arthur LLP
250 East Fifth Street, Suite 2200
Cincinnati, Ohio 45202
(513) 369-4224